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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,815	09/08/2003	Methvin Isaac	317743-121	1150

39731 7590 06/06/2005

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EXAMINER

DENTZ, BERNARD I

ART UNIT PAPER NUMBER

1625

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,815

Applicant(s)

ISAAC ET AL.

Examiner

Bernard Dentz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-11 and 14-21 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

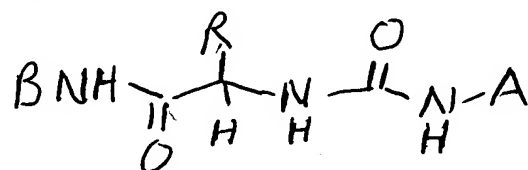
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2-9-2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: 5 references

Applicants have elected Gp. I, claims 1-6, 8-11 and 13-21 without traverse. Applicants have cancelled the non-elected material from the generic claims. Non-elected claim 7 is withdrawn from consideration.

In the carbamoylmethyl urea derivatives taught by the references are denoted by the following formula:



1 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Danielsson et al. It discloses at the top of p.147 the synthesis of the compound where A is phenyl, R is H and B is 2,6-dimethylphenyl.

Claims 1,2,5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwakura et al. It discloses at p. 1159, bottom of col. 2, the syntheses of compounds where A and B are p-ethoxyphenyl and, R is H, methyl or sec-butyl and wherein A and B are phenyl and R is isopropyl or benzyl.

Claims 1,2, 5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Khorana. It discloses the synthesis at p. 2082 and 2083 (V) and (XIII) the

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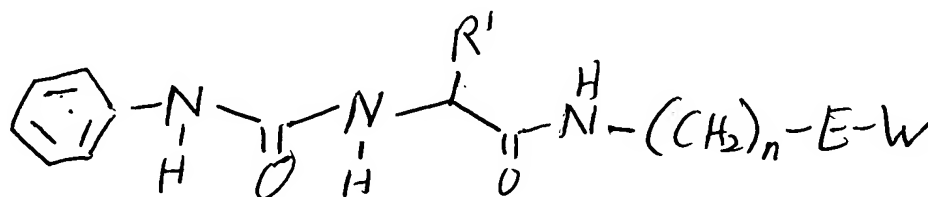
compounds where A and B are p-methylphenyl and R is H, i-propyl or benzyl. It also discloses the synthesis at p. 2083 of XVII where A and B are 4-methylaminophenyl and R is H and the compound where A is cyclohexyl, b is phenyl and R is H. They name the previous compound (N-cyclohexylcarbamyl)glycine anilide.

Claims 1,5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Svetkin. It discloses the synthesis at p. 842 of the instant compounds where A is phenyl, B is phenyl, 2-methylphenyl or 4-methylphenyl and R is H. See compounds 8-10 (counting down) in the Table under Experimental on p. 842.

Claims 1,2, 15 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hagishita et al. It discloses as the synthesis of compound 11 at p. 1697 where A is 3-methylphenyl, B is 2-iodophenyl and R is H. It is used as an intermediate in the preparation of gastric acid secretion inhibitors, which are not within the scope of the instant claims.

The references cited above were all in the International Search Report

Claims 1-3, 5, 8, 10, 11, 14-18, 20 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Dorsch et al, WO 02 48099 cited by applicants. It discloses a genus including compounds of the formula



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useful in treating thrombosis. See the preferred sub-genus in the paragraph bridging p. 12 and 13 when n is 0, E is 1,4-phenylene and W is dimethylamino, diethylamino, piperidin-1-yl or morpholinyl. See Ex. 3 on p.37 and 38 and Ex. 18 and 19, etc. Note that the phenyl moiety on the ureido N can be substituted by hal, alkyl, alkoxy, alkenyl, various amino groups, nitro, etc. Thus the instant compounds where AR1 is phenyl or phenyl substituted with the above groups are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 8, 10, 11, 14, 15, 17, 18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorsch et al, supra. Note that analogs and homologs of the specific compounds taught by the reference would have been obvious. Note also that the instant generic concepts wherein R1 is aryl substituted with NR8R9 would have been obvious.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-11 and 14-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In 1: at line 9 alkylene oxide should be alkyleneoxy; after nitro in line 23 a comma is missing; and in line 35 after " haloalkyl," -C(O)R₁₂, should be inserted. In applicants' amendment to the specification at p. 4, line

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21 to p. 5, line 3, also denoted as par. 16 at line 4 of it "alkylene oxide" should be - - alkyleneoxy- -.

In the amendment to the specification of p. 5, lines 28 to p. 6, line 5, also denoted as par. 24, at line 5 after "haloalkyl" - -, $C(O)R_{12}$ - - should be inserted.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Treating a patient having a medical condition for which a glycine transport inhibitor is indicated is not enabled. One of ordinary skill in the art would not know what diseases are treatable. Applicants should insert - - selected from schizophrenia, cognitive dysfunction or Alzheimer's disease- - after "indicated" in claim 15 and cancel claim 16.

Claim 13 would be allowable if presented in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dentz

5-26-2005



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